

1 A CHEMICAL COMPOSITION FOR AIDING
2 THE ABSORPTION, BINDING AND ELIMINATION OF UNDIGESTED FAT
3

4 BACKGROUND OF THE INVENTION

5 Claim of Priority

6 The present application is a continuation-in-part of a
7 previously filed, currently pending U.S. patent application,
8 namely, that having Serial No. 10/237,546 and filed on September
9 9, 2002 and which is now set to issue as U.S. Patent No.
10 6,703,419 on March 9, 2004, which is a continuation-in-part of
11 an earlier filed patent application having Serial No. 09/808,646
12 and filed on March 13, 2001 and which is now U.S. Patent No.
13 6,447,812, which is a continuation-in-part of an earlier filed
14 patent application having Serial No. 09/521,224 filed on March
15 8, 2000 and which is now U.S. Patent No. 6,200,574, which itself
16 was a continuation-in-part of an earlier filed patent
17 application, namely, Serial No. 09/135,920 filed on August 18,
18 1998 and which is now U.S. Patent No. 6,048,532, which itself
19 was also a continuation-in-part of an earlier filed patent
20 application, namely, Serial No. 08/888,848 filed on July 7, 1997
21 and which matured into U.S. Patent No. 5,795,576 on August 18,
22 1998, and for which a claim of priority was made under 35 U.S.C.
23 Section 119(e) to an earlier filed, provisional patent
24 application having Serial No. 60/021,299 filed with the U.S.
25 Patent Office on July 8, 1996. Each of these earlier patent

1 applications are incorporated fully herein by reference.

2

3 Field of the Invention

4 The present invention relates to a chemical composition and
5 a method for aiding in absorbing and binding undigested fat for
6 rapid elimination from the human body, and thereby assisting
7 weight loss in humans. In accordance with the present
8 invention, a human ingests the chemical composition in
9 recommended dosages, preferably prior to eating a meal, so as to
10 facilitate the binding of undigested fat to a fibrous agent for
11 rapid elimination from the human body.

12

13 Description of the Related Art

14 In this day and age, many people's lifestyles have become
15 less physically active due at least in part to the increasing
16 demands of modern society. A natural result of a sedentary
17 lifestyle is the tendency to gain weight. Indeed, it is now
18 commonly thought that many people are over-weight and further,
19 that obesity is becoming a growing problem. Due to this trend,
20 countless efforts have been made to help people control their
21 weight. As a few examples, many have proclaimed to have won the
22 "battle of the bulge" with a specific diet program or a
23 particular exercise program. Others have explored hypnosis and
24 other mechanisms for controlling the appetite of an individual.
25 Still others in the scientific arena have formulated sugar

1 substitutes and are pursuing fat substitutes as methods to
2 reduce the caloric intake of an individual hopefully, without
3 sacrificing the taste of otherwise highly fattening foods.
4 While these efforts are generally capable of aiding many in
5 their fight to lose weight or to maintain a desired weight, many
6 are in general, ineffective or simply not practical. For
7 example, some good meaning souls have tried in earnest to follow
8 a particular diet plan but eventually, fall off the plan lacking
9 will-power to continue for weeks and months at a time. This is
10 equally true of those who try hypnosis and similar weight-loss
11 gimmicks. Finally, some view sugar substitutes as being
12 tasteless or worse, as carrying an intolerable health risk,
13 given that some studies have linked them to carcinogens and/or
14 the formation of brain tumors.

15 It has been appreciated in recent years that the fat
16 content of foods eaten are a major culprit behind human weight
17 gain. For example, regardless of the type of fat present in a
18 food product, fat has the highest caloric value per gram --
19 about 9 calories per gram -- of any food group. It is understood
20 that the body tends to store fat for future use, rather than to
21 utilize it immediately, and this factor helps lead to weight-
22 gain. Additionally, in recent years it has further been
23 recognized that there is a connection between the amount of fat
24 stored in the body and the level of cholesterol in the body. A
25 diet high in fat is more likely to result in the development of

1 higher cholesterol levels. As cholesterol has been indicated as
2 a factor in arteriosclerosis or hardening of the arteries, the
3 risk for heart disease and/or a heart attack is elevated when a
4 diet high in fat is followed. Unfortunately, fat also makes
5 many food items more tasty -- whether butter on bread, dressings
6 on salads, sour cream on potatoes, or frosting on cake -- and
7 are, therefore, difficult to eliminate entirely from one's diet.
8 Thus, fat usually finds its way into the body. Once it does so,
9 a healthy body automatically secretes lipase, an enzyme that
10 accelerates synthesis of fats, i.e., breaking down the fat
11 molecule. The majority of all fats in foods are present in
12 "triglyceride form", which the body seeks to break down by
13 removing the glycerol molecule from the triglyceride and
14 thereby, release the free fatty acids. Once this occurs, the
15 body is well on its way to absorbing the fat and likely, storing
16 same instead of utilizing it for energy.

17 From the foregoing, it will be understood that there
18 remains an appreciable need in the art for a product which
19 facilitates a person's efforts to lose weight and/or to control
20 his or her weight and yet which is safe and easy to implement.
21 There remains a need in the art for a product and method which
22 aids a person in losing weight or in maintaining a stable
23 weight, which does not rely exclusively on will power. Any such
24 product or method should not interfere with the taste of foods.
25 It would further be beneficial for any such product or method to

1 remain effective even when the person ingests the product just
2 prior to a meal. Ideally, any such product or method would
3 permit a person to eat the foods that they most like, without
4 being overly mindful of the fat content contained therein.
5 Preferably, any such product or method would prevent the body
6 from absorbing the fat in such foods once they have been eaten
7 and further, would aid the body in rapid elimination of the
8 absorbed fats in a safe and comfortable manner. In turn, the
9 rapid elimination of fats subsequent to ingestion and prior to
10 digestion, would have a highly beneficial effect in preventing
11 the build-up or accumulation of harmful cholesterol. The
12 present invention is designed to satisfy the needs in the art
13 and is believed to represent a significant advance in improving
14 a person's health by facilitating weight loss through the rapid
15 elimination of the fat from the human body.

16

17 Summary of the Invention

18 The present invention provides a novel, chemical
19 composition for ingestion by humans which facilitates weight
20 loss and fosters the maintenance of a stable weight in humans,
21 although the invention should not be construed so as to be
22 limited to use with humans. In particular, when the chemical
23 composition of the present invention is ingested by a human
24 prior to eating a meal, the composition acts to absorb and bind
25 undigested fat to a fibrous agent so as to promote its rapid

1 elimination from the human body.

2 In accordance with this invention, the novel composition is
3 moisture activated such that it remains inert and can be formed
4 into capsules, preferably conveniently sized for ingestion by a
5 human, and will remain inert until it comes into contact with
6 water, bodily fluids or other liquids. In one embodiment, the
7 composition of the present invention comprises a mixture of a
8 fibrous agent, preferably psyllium husks, in generally an amount
9 of between 72% and 88% by weight of the total chemical
10 composition, natural marine shellfish extract generally in an
11 amount of between 9% and 11% by weight of the total chemical
12 composition, acacia generally in an amount of between 4.5% and
13 5.5% by weight of the total chemical composition, apple pectin
14 generally in an amount of between 1.4% and 2.2% by weight of the
15 total chemical composition, ascorbic acid, better known as
16 Vitamin C, generally in an amount of between 1.8% and 2.2% by
17 weight of the total chemical composition, and an excipient such
18 as, but not limited to, magnesium stearate generally in an
19 amount of about 1% by weight of the total chemical composition.
20 Upon contact with moisture, the composition begins to break down
21 and becomes activated. Once activated, the composition acts
22 quickly, usually within 30 seconds to seek and attach itself to
23 undigested fats such as oils and the like, and typically, within
24 about 2 minutes will form a small mass of undigestible fibrous
25 material.

1 Additionally, a method for using the chemical composition
2 is also described, which comprises the steps of forming a
3 capsule or tablet containing between about 500 and 700
4 milligrams of the chemical composition and having a human ingest
5 at least one to four of these capsules with generally about
6 eight ounces of water generally about fifteen to about twenty
7 minutes before a meal.

8 The present invention provides a chemical composition and
9 method of treatment which serve as a convenient and effective
10 means for reducing the quantity of fat digested and/or absorbed
11 by the human body.

12 Also, the present invention provides a chemical composition
13 which seeks out, attaches and binds undigested fat ingested by
14 a human to a fibrous agent, forming an undigestible mass which
15 can easily and rapidly be eliminated from the human's body.

16 The chemical composition of the present invention is
17 moisture activated and therefore, is inert and can be formed
18 into and stored as conveniently sized capsules, each containing
19 generally between about 500 and 700 milligrams of the chemical
20 composition, until being ingested by a human and activated by
21 coming into contact with bodily secretions whether water or
22 other liquid.

23 The present invention further provides a chemical
24 composition which includes at least one fibrous material for
25 aiding the human body in rapid elimination of waste.

1 A capsule containing approximately 500 milligrams of the
2 chemical composition of the present invention can absorb up to
3 twelve times its own weight or generally about 3 to 6 grams of
4 undigested fats.

5 These and other objects, features and advantages of the
6 present invention will become readily apparent from the detailed
7 description, which follows.

8

9 Detailed Description of the Preferred Embodiment

10 The present invention is directed towards a chemical
11 composition for ingestion by humans which acts to absorb and
12 bind undigested fat and rapidly eliminate the undigested fat
13 from the human body. The present invention is also directed to
14 a method of aiding weight loss in humans.

15 The chemical composition of the present invention primarily
16 comprises at least one fibrous agent to act both as a vehicle
17 for absorbing fat and as a medium for allowing a human to feel
18 full. The fibrous agent may include any of a number of
19 compounds including, but not limited to, psyllium, bran, ideally
20 but not necessarily oat bran, the husks of natural oat bran
21 seeds, as well as plantago ovata seed mucilage. Additional
22 embodiments of the composition of the present invention are
23 envisioned which may comprise one or more other fibrous agents.

24 At least one embodiment of the chemical composition
25 comprises psyllium husks, a purified fiber product obtained from

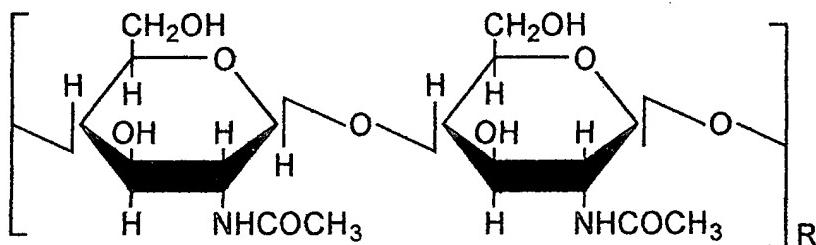
1 the dilute acid extract from the seeds of *plantago ovata*, as the
2 fibrous agent. In a preferred embodiment, the psyllium husks
3 comprise generally an amount of between 72% and 88% by weight
4 and, ideally, an amount of about 80% of the total chemical
5 composition. As previously indicated, however, it remains
6 within the scope of the present invention for the chemical
7 composition to comprise one or more other fibrous agents.

8 In addition to a fibrous agent, a preferred embodiment of
9 the chemical composition of the present invention comprises
10 natural marine shellfish extract ("NMSE"). In one preferred
11 embodiment, NMSE is included generally present in an amount of
12 between 9% and 11% by weight, and ideally, in an amount of about
13 10% by weight of the total chemical composition. The NMSE is
14 obtained from shellfish such as, for example, crabs, shrimp,
15 and/or lobsters, which are initially exposed to a
16 deproteinization process comprising a dilute, approximately
17 3.5%, sodium hydroxide solution, which is maintained at a
18 temperature between 80 and 90 degrees Celsius, into which the
19 shellfish are placed for approximately 3 hours. Next, the
20 shellfish are decalcified in a dilute, approximately 5% to 7%,
21 hydrochloric acid solution, maintained at room temperature for
22 approximately 2 hours. The shellfish are then deacylated in a
23 concentrated, approximately 46% to 48%, sodium hydroxide
24 solution, at a temperature between 85 and 95 degrees Celsius for
25 a period of anywhere from 8 to 20 hours. Once the shellfish

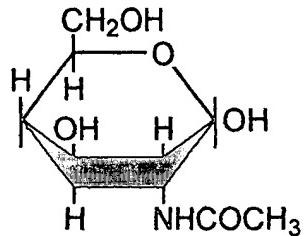
1 have been deacylated, the remaining extract is washed, dried,
2 and is reduced to a powder form, ready for consumption.

3 An alternate embodiment of the present invention may
4 comprise glucosamine, a form of the natural marine shellfish
5 extract derived from deacetylated shellfish shells or chitin.

6 Chitin is known in the art as a naturally occurring
7 polysaccharide -- a polymer of long molecules consisting of
8 sugar molecules strung together as shown by the general formula:

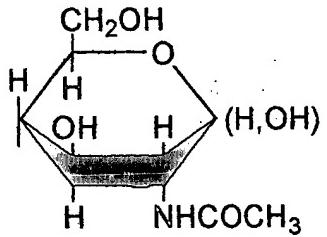


15 Chitin, which can be obtained from crab, lobster or shrimp
16 shells by dissolving the shells' with calcium carbonate and then
17 removing protein fragments, leaving behind chitin as a white
18 powder, normally cycles through the environment, decomposing
19 naturally into its hydrogen, carbon, nitrogen and oxygen
20 building blocks. In one process, glucosamine may be obtained
21 from chitin by hydrolysis. Specifically, glucosamine salts and
22 compounds are derived from a monomer of chitin, namely, N-
23 acetyl-D-glucosamine (GlcN Ac) which is represented by the
24 general formula:



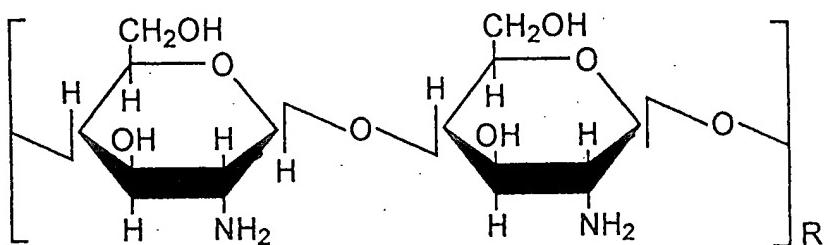
6 and will be utilized such as, for example, glucosamine
7 hydrochloride, acetylated glucosamine, and/or D-glucosamine.
8 Glucosamine hydrochloride has been shown to be an efficacious
9 alternative to corticosteroid treatment of enteritis and
10 colonitis. It will be understood by those of ordinary skill in
11 the art that as a derivative of chitosan, which has an ability
12 to chelate various metal ions because its hydroxy and amino
13 groups act as electron donors, glucosamine HCl is an ion, or a
14 molecule having a negative charge which, therefore, attracts and
15 binds with certain molecules of food. In another alternate
16 embodiment, a beta-alkylglycoside of N-acetyl-D-glucosamine may
17 be utilized, which is represented by the general formula:

18



24 and is believed to effectively increase the ability of one's
25 digestive tract to handle substantial quantities of lactose. In

yet another alternate embodiment, the composition may comprise the natural marine shellfish extract in the form of chitosan which is obtained by subjecting chitin, in white powder form, to a concentrated sodium hydroxide solution heated to above 135 degrees Celsius to remove one of chitin's side groups, i.e., to hydrolize the N-acetyl, which can be more readily dissolved. Chitosan, which is represented by the general formula:



also has the ability to act as a coagulant, i.e., to attract and bind with certain molecules, such as amino acids and proteins.

A preferred embodiment of the present invention comprises the natural marine shellfish extract in the form of a high density chitosan. More in particular, most commercially available chitosan, such as may be obtained from the white powder form of chitin, as described above, has a bulk density of generally about 0.2 grams per cubic centimeter (g/cc). In the present and preferred embodiment, the NMSE comprises a high density chitosan having a bulk density of generally about 0.3 g/cc. One further preferred embodiment comprises a high density chitosan having a tap density of approximately 0.4 g/cc, the tap

density being obtained by repeatedly tapping an amount of the material in a volumetric container so as to minimize the interstitial spaces between particles of the material until an essentially constant volume of the material is achieved. One advantage imparted by the high density chitosan is its improved solubility characteristics, which allows the chemical composition of the present invention to perform effectively even when the person ingests the composition just prior to eating a meal.

In addition to psyllium husks and NMSE, at least one embodiment of the present invention comprises acacia, more commonly known as karaya gum, generally in an amount of between 4.5% and 5.5% by weight of the total chemical composition. The acacia serves the purpose of providing lubrication and as well as providing an additional fibrous agent to the composition. In a preferred embodiment, acacia comprises an amount of about 5% by weight of the total chemical composition. An alternate embodiment of the present invention comprises glucomannan, also known as Konjak or Konjac Root, in lieu of acacia.

In addition, a preferred embodiment of the chemical composition also comprises a pectin obtained from fruits or vegetables which serves the purpose of providing an additional fibrous agent to the composition. The fruit or vegetable pectin is included in the chemical composition and comprises generally an amount of between 1.4% and 2.2% by weight. In a preferred

1 embodiment, an apple pectin is included in amount of about 2% by
2 weight of the total chemical composition.

3 The preferred embodiment of the composition also comprises
4 ascorbic acid, better known as Vitamin C, generally in an amount
5 of between 1.8% and 2.2% by weight, and ideally, in an amount of
6 about 2% by weight of the total chemical composition. Ascorbic
7 acid (Vitamin C) is provided in the preferred chemical
8 composition to enhance the binding ability of the NMSE,
9 glucosamine HCl, chitosan, and/or high density chitosan.

10 Finally, at least one embodiment of the present invention
11 comprises an excipient, for example, magnesium stearate, which
12 serves to make the resultant composition smooth. In one
13 preferred embodiment, the excipient comprises an amount of about
14 1% by weight of the total chemical composition. The chemical
15 composition of the present invention may comprise other
16 excipients including, but not limited to, a saturated fatty
17 acid, such as stearic acid, hydroxypropylmethylcellulose, guar
18 gum, methyl cellulose, and/or silicon dioxide, for the purpose
19 of making the composition smooth.

20 In the most preferred embodiment, the psyllium husks, NMSE,
21 acacia, apple pectin, ascorbic acid (Vitamin C), and the
22 excipient are mixed together in powder form, although a granular
23 form might also be suitable, which results in a mixture which is
24 inert until it comes into contact with water, or another liquid,
25 such as is produced by the human body during digestion. Thus,

1 in the most preferred embodiment, the present invention can be
2 formed into capsules so as to facilitate packaging, storage and
3 ingestion. Additionally, the material used to form the
4 encasement of the capsule will be inert and upon coming into
5 contact with water or other liquid, will begin to break down and
6 permit both the release and activation of the chemical
7 composition. If desired, the capsules containing the chemical
8 composition according to the present invention may be packaged
9 into bottles containing 50, 60, 75, 80, 100 or more capsules,
10 and may include a small, separately wrapped quantity of a drying
11 agent, such as a silica gel in order to aid dry conditions for
12 preserving the composition inert until use by a human.

13 In one preferred embodiment of the present invention, a
14 white opaque capsule, size No. 0, having a weight of
15 approximately 100 milligrams (mg), is filled with a mixture
16 comprising approximately 400 mg of psyllium husks; 50 mg of
17 NMSE; 25 mg of acacia; 10 mg each of apple pectin and ascorbic
18 acid (Vitamin C); and 5 mg of excipient, thereby yielding a
19 capsule having a total weight of approximately 600 mg, and
20 containing approximately 500 mg total of the chemical
21 composition of the present invention. It will be appreciated
22 that a capsule containing about 500 mg of the chemical
23 composition has a size and overall dimension which is readily
24 suited for being comfortably swallowed by a person, although the
25 capsule could be formed to contain more or less of the chemical

composition (with the ratios of the ingredients of the chemical composition similar to that disclosed herein), and thereby be somewhat larger or smaller, and still function in the intended manner when ingested by a person. Testing performed with the above described chemical compositions have demonstrated the ability to absorb up to 12 times its own weight or about 3 to 6 grams of undigested fats. For instance, in one experiment 70 milliliters of water was placed in an appropriately sized test tube along with 2 grams of wheat germ oil and 100 mg of lecithin. This mixture was shaken vigorously for about 10 seconds. Next, 1,000 mg of the chemical composition according to one embodiment of the present invention (two capsules containing 500 mg each) were added and again, the mixture was shaken vigorously for about 10 seconds. After several minutes, the mixture was observed as having approximately ninety-five (95%) percent of fat (oil layer) gone, i.e., fat was no longer visible but instead had become bound with the fibrous agent of the composition so as to form an undigestible mass.

In addition, the chemical compositions of the present invention lend themselves to a method of aiding human weight loss, which will now be described. In particular, the chemical compositions of the present invention seek out and bind with fat ingested by a human prior to its being absorbed into the body, and as has been explained, binds them to a fibrous agent so as to aid the person in feeling "full" and further, to permit rapid

1 elimination by the human body.

2 A preferred method of the present invention comprises the
3 steps of forming a capsule containing about 500 mg of the
4 preferred chemical composition and having the human ingest at
5 least one of the 500 mg capsules with generally about eight
6 ounces of water generally about fifteen to twenty minutes before
7 a meal. Ideally, the human will ingest one or two of the
8 capsules before a meal, but may ingest up to about four of the
9 capsules, or 2,000 mg of the chemical composition, if the meal
10 to be eaten is especially large and/or has a particularly high
11 fat content. Upon being ingested by a human, each capsule
12 begins to disintegrate and releases or otherwise facilitates
13 activation of the chemical composition contained therein,
14 typically in about thirty (30) minutes, and often in less time.
15 In one preferred embodiment of the present method, there is an
16 additional step of having the human ingest generally about eight
17 ounces of water upon waking up in the morning, and ideally,
18 there is an additional step of having the human ingest generally
19 about eight ounces of water between meals.

20 Another embodiment of the method of the present invention
21 utilizes capsules containing about 700 mg of the chemical
22 composition comprising psyllium husks generally in an amount of
23 between 72% and 88% by weight of the total chemical composition,
24 natural marine shellfish extract generally in an amount of
25 between 9% and 11% by weight of the total chemical composition,

1 acacia generally in an amount of between 4.5% and 5.5% by weight
2 of the total chemical composition, apple pectin generally in an
3 amount of between 1.4% and 2.2% by weight of the total chemical
4 composition, ascorbic acid (Vitamin C) generally in amounts of
5 between 1.8% and 2.2% by weight of the total chemical
6 composition, and the excipient generally in an amount of about
7 1% by weight of the total chemical composition. In this
8 embodiment of the present invention, the capsule could be formed
9 to contain more or less of the chemical composition (with ratios
10 of the ingredients of the composition being similar to that
11 disclosed herein), and thereby be somewhat larger or smaller and
12 still be adequate for ingestion by a person.

13 In addition, this latter embodiment of the chemical
14 composition of the present invention also lends itself to a
15 method of aiding human weight loss by seeking out and binding
16 with a fat ingested by a human prior to the fat being absorbed
17 by the body. As has been explained, the fat binds to the
18 fibrous agents of the composition so as to aid the person in
19 feeling full, and further permits the rapid and natural
20 elimination thereof from the human body. One method utilizing
21 this latter embodiment of the present invention comprises the
22 steps of forming a capsule containing about 700 mg of the
23 chemical composition and having the human ingest at least 4 of
24 the 700 mg capsules with generally about 8 ounces of water,
25 approximately 15 to 20 minutes before a meal is to be consumed.

1 From the foregoing, it should be clear that a human may ingest
2 more than 4 of such capsules and even up to 6 or more of such
3 capsules, if the meal to be eaten is especially large and/or has
4 a particularly high fat content. Upon being ingested, each
5 capsule begins to disintegrate and releases the chemical
6 composition contained therein, in generally about 30 minutes and
7 often less time. In one form of the method of the present
8 invention utilizing this latter embodiment, there is an
9 additional step of having the human ingest generally about 8
10 ounces of water upon waking in the morning and ideally, there is
11 an additional step of having the human ingest about 8 ounces of
12 water between meals.

13 Since many modifications, variations and changes in detail
14 can be made to the described preferred embodiment of the
15 invention, it is intended that all matters in the foregoing
16 description be interpreted as illustrative and not in a limiting
17 sense. Thus, the scope of the invention should be determined by
18 the appended claims and their legal equivalents.

19 Now that the invention has been described,